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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,307

09/25/2003

Jay E. Birnbaum

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05/15/2006

Bradley N. Ruben, PC  
Suite 5A  
463 First Street  
Hoboken, NJ 07030

EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,307	<b>Applicant(s)</b> BIRNBAUM, JAY E.	
	<b>Examiner</b> Eric E. Silverman, PhD	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 - 15 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: ____ | 6) <input checked="" type="checkbox"/> Other: <u>MP</u>                                |

### DETAILED ACTION

Receipt of Applicants' amendments and remarks, filed 3/14/06, is acknowledged.

Claims 1 – 15 are pending in this action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 6, and 9 – 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claim 1 as amended now recites "sufficiently hard for insertion between the nail plate and the hyponychium". The specification supports sufficiently hard for insertion between the nail plate and the nail bed in the section referenced in applicants' response. However, hyponychium is not synonymous with the nail bed; it is one part of the nail bed (see the entry from Stedman's Medical Dictionary, cited on PTO 892). A careful review of the remainder of the originally filed disclosure shows no support for the amendment as written. Claims 9 – 12 are rejected for depending on claim 1 and thus incorporating the new matter thereof.

Claim 6 recites "without penetrating the nail plate". A careful review of the originally filed disclosure reveals no support for this limitation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 8, 13 and 14 under this statute, as discussed in the previous office action, are moot in view of the amendment. However, because of the amendment, the following rejections are deemed necessary.

Claims 1, 9 – 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

After the amendment, claim 1 recites "being sufficiently hard for insertion between the nail plate and the hyponychium". It is not clear, and the specification provides insufficient guidance, as to how hard the carrier would have to be to have the recited property. The specification gives only a few examples of materials that are sufficiently hard, but does not give any substantial information that would allow the artisan to know what substances, outside of the limited examples, would also be sufficiently hard, as required.

Further, it is unclear whether the modifier "being sufficiently hard for insertion between the nail plate and the hyponychium" applies to the carrier alone or to the composition as a whole. Clarification is requested.

Claims 9 – 12 are rejected for depending on claim 1 without clarifying these issues.

After the amendment, claim 14 recites “flowable forced”. This term is not well understood. As such, the artisan would not be able to determine the metes and bounds of the claim. It is possible that applicant intends to recite “flowable and forced”. Clarification is requested.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 9 – 11 **remain** rejected under 35 U.S.C. 102(e) as being anticipated by US 6,846,837 to Mailbach for reasons of record and those discussed below.

***Response to Arguments***

Applicants’ arguments have been fully considered, but are not persuasive. Applicants’ argue that since Applicant coined the term subungicide Mailbach cannot disclose a subungicide. It is noted, however, that the composition of Mailbach fits the definition of subungicide in instant application, for reasons discussed in the prior action, and thus Mailbach’s composition is a subungicide as defined in instant application, other phraseology used to describe the same thing notwithstanding. With regard to the notion that Mailbach’s composition is intended for different uses than that of instant claims, it is noted that the intended use of a composition does not impart patentability thereon.

Applicant also argues that Mailbach's composition is not disclosed to be "sufficiently hard for insertion between the nail plate and the hyponychium", as the claim now requires. However, absent a definition of what hardness is "sufficiently hard", as claimed (*vide supra*), at least the plaster disclosed by Mailbach is deemed to be "sufficiently hard", as claimed.

The rejection of claims 1 and 9 under 35 U.S.C. 102(b) as being anticipated by US 4,180,058 to Brem are **withdrawn**.

Applicant's arguments are partially persuasive. Specifically, Applicants' arguments that the composition of Brem is not a semi-solid is noted.

Claims 2 – 5, 9, 13, and 15 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by US 4,180,058 to Brem for reasons of record and those discussed below.

### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive. Applicant argues that Brem does not force the antifungal agent past the hyponychium to end up in contact with the nail bed, as required by claim 2. However, it is noted that in the method of Brem, the antifungal agent is forced past the hyponychium, specifically, the agent is forced past the portions of the nail plate adjacent to the holes drilled therein. With respect to Applicants' argument that the number of holes drilled in the nail plate discredits the notion that the antifungal composition is drawn between the nail plate and the nail bed, it is believed that the number of drilled holes actually serves to support this

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notion. Specifically, it is noted that in the method of Brem, the fungus under the nail plate is disclosed to be completely treated. Thus, the fungal infection which is under the portion of the nail plate that is *not* removed by drilling is also treated. As such, it follows that the antifungal composition must flow under the portions of the nail plate that remain after drilling in order to treat all of the fungal infection. If this were not the case, the method of Brem would not be effective, and the entire nail plate would have to be removed in order to treat the infection. In the previous office action, capillary action was proposed as a convenient mechanism that would likely explain the effectiveness of Brem's method. However, regardless of whether or not capillary action is the force responsible, it is clearly inherent in the method of Brem that some of the antifungal agent will reside between the nail plate and the nail bed.

Examiner notes the following section of MPEP 2112.

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or in technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

The above explanation, in addition to that provided in the prior office action, is a sufficient showing of fact (the observation that Brem's method is effective without requiring removal of the entire method) and technical reasoning (the well-understood phenomenon of capillary action, which is likely responsible for this observation) to reasonably support the determination that, in the method of Brem, the characteristic of antifungal agent being between the nail plate and nail bed inherently flows from the teachings of the prior art.

As such, with regard to Applicants' demand that the Examiner show further support for this determination, the following section of MPEP 2112 is further noted.

**V. ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION, AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE**

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on *prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

***Claim Rejections - 35 USC § 103***

The rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over US 4,180,058 to Brem is **withdrawn** in light of the amendment.

***Response to Arguments***

Applicants' arguments have been fully considered and are persuasive. Brem does not disclose or suggest a method that does not entail penetration of the nail plate.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric E. Silverman, PhD  
Art Unit 1615



MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600